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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,499	02/07/2002	Konstantin Petrukhin	20430P	2080

210 7590 09/13/2006

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,499	PETRUKHIN ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *7-15 and 17-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *notice to comply*.

DETAILED ACTION

1. Applicant's election with traverse of group I, drawn to isolated DNA, claims 1-6 and 16, in the reply filed on 6/26/05 is acknowledged. Applicant has further elected SEQ ID NO: 1 as the species of DNA sequence.

Applicant's traversal is on the grounds that it would not be an undue burden to additionally examine groups IV and V. This is not found persuasive because undue burden is irrelevant to the restriction practice for cases filed under 35 U.S.C. 371 (see MPEP Chapter 1800).

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-15 and 17-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) set forth below:

The CRF incorrectly list the filing date of the instant application as 9/2/01, when the filing date is actually 2/7/02.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, "stringent conditions" is a relative term that renders the claims indefinite. The term is not defined by the claim or the specification, and the metes and bounds of the claims cannot be established.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of DNA molecules "comprising nucleotides encoding a KCNQ5 protein" or DNA molecules that "hybridize under stringent conditions" to SEQ ID NO: 1 and SEQ ID NO: 2.

The instant claims encompass DNA molecules that encode a KCNQ5 protein. This might encompass DNA molecules encoding KCNQ5 proteins from a variety of different species, for example mouse, human, rat, dog, horse, etc. In addition, the claims might encompass DNA molecules that encode splice variants or polymorphic variants of KCNQ5. Furthermore, the claims encompass DNA molecules comprising "nucleotides" encoding a KCNQ5 protein. This might include short nucleotide sequences which encode a KCNQ5 protein fragment. Furthermore, the DNA molecule encoding the various species homologs, splice variants, or fragments would all have different structures due to their unique nucleotide sequence. In contrast to the broad genus of structurally different nucleic acid molecules encompassed by the claims, the instant specification only discloses the genomic and cDNA sequences encoding human KCNQ5 (i.e., SEQ ID NO: 1 and SEQ ID NO: 2).

Additionally, the instant claims encompass DNA molecules that "hybridize under stringent conditions" to SEQ ID NO: 1 and SEQ ID NO: 2. This might reasonably encompass structurally different DNA molecules, including those encoding KCNQ5 homologs from other species, splice variants, and fragments, as described above. Additionally, the instant specification does not disclose a single species of DNA that hybridizes under "stringent conditions" to SEQ ID NO: 1 and SEQ ID NO: 2. Thus, one of

skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent 6,492,505 (of record).

The '505 patent discloses a DNA sequence that is 100% identical to SEQ ID NO: 1 of the instant application over ~400 residues (see SEQ ID NO: 303 of the '505 patent). Given the high degree of homology, said DNA would hybridize to SEQ ID NO: 1 under stringent conditions. Additionally, said DNA comprises at least 18 contiguous nucleotides of SEQ ID NO: 1, and can be used as a probe (see column 6, in particular). Furthermore, SEQ ID NO: 303 of the '505 patent encodes amino acids 490-658 of SEQ ID NO: 3 (i.e. comprises "nucleotides" encoding SEQ ID NO: 3 or a KCNQ5 protein). SEQ ID NO: 303 also comprises "a nucleotide sequence" of SEQ ID NO: 1 (for example, residues 123676-124045 of SEQ ID NO: 1). The '505 patent also teaches plasmids (i.e. vectors) and host cells comprising said DNA (see column 7 and 16-17, in particular).

Thus, the reference clearly anticipates the invention.

7. Claims 1-4 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/41010.

WO 96/41010 teaches DNA molecules (i.e. probes) comprising 19 contiguous nucleotides of SEQ ID NO: 1 (see SEQ ID NO: 70 or

72 in particular). Furthermore, said DNA molecules would hybridize under "stringent conditions" to SEQ ID NO: 1. Furthermore, said DNA molecules comprise "nucleotides" encoding SEQ ID NO: 3 or a KCNQ5 protein. SEQ ID NO: 70 and 72 also comprise "a nucleotide sequence" of SEQ ID NO: 2 (for example, residues 124564-124581 of SEQ ID NO: 1).

Thus, the reference clearly anticipates the invention.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
Technology Center 1600
August 9, 2006

8/13/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER

Notice to Comply	Application No. 09/937,499	Applicant(s) PETRUKHIN ET AL.	
	Examiner Amy E. Juedes, Ph.D.	Art Unit 1644	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: see attached office action.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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